

3D printed titanium implants: colossal FDA-approved leap towards “personalized” maxillo-facial surgery.

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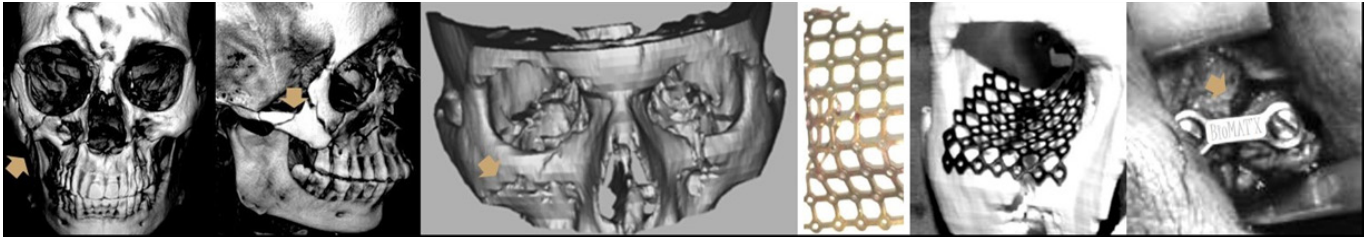
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Global health initiatives, over the last years, have often struggled to implement impactful vicissitudes, whether in preventive or interventional, and more so, surgical care¹. This can be mainly attributed to (a) deficiencies in comprehending what aspects govern the capacity of a surgical service to deliver safe, efficacious, accessible, and cost-effective care; and (b) whether the surgical service/care meets the mounting needs and demands of populations.¹⁻³ For example, the past decade was declared by the World Health Organization (WHO) as *the Bone and Joint Decade (2000-2010)*, in light of the dramatically-perturbing high indices and accumulating costs of musculoskeletal-related conditions; whether due to trauma, defects, deficiencies, pathologies and/or ageing.⁴ Indeed, in 2009, more than 8 million fracture repair procedures were performed globally (with reports of more than 50 million new fractures taking place World-wide every year). Such indices do not seem likely to slow, in light of mounting demographics and longevity.³

Hence, efforts and resources intensified the pursuit for novel technologies, materials and methods to deliver better alternative therapeutic options for the growing World populace, and to improve the Quality of Life (QoL) of patients, while trying to reduce healthcare spending: costs of surgical procedures, recovery treatments and medical/dental devices.⁴

The American Society of Maxillofacial Surgeons (Available at: <http://maxface.org/conditions-and-treatments/dentofacial-anomalies-treatment.cgi>) describes dento-facial anomalies as abnormalities in dental and facial growth that affect children and adults; with cleft lip/palate and craniofacial macrosomia, as the two most commonly conditions often tackled at specialized craniofacial centers. Such cases, although not life-threatening, can still affect psycho-social function and over-all QoL, severely. Indeed, whether the existing facial deformity is congenital or acquired (mainly due to either trauma or post-tumor surgery), the general QoL negative impact to the patient as well as his/her family is significant. Furthermore, proper dento-facial and physical appearance equate happiness and/or success in life; especially during adolescence and early adulthood. Hence, the correction of dentofacial anomalies to restore and/or improve functional (occlusal) as well as aesthetic profiles are critical to our patients, their caregivers, families, friends and acquaintances. The treatment of dento-facial anomalies is expected to result in a radical change for the better, in terms of both masticatory system-related aspects: appearance

Figure 1. Illustration case.



Le Fort I maxillary and right zygomatico-maxillary complex fracture (a,b) CBCT 3-D reconstruction frontal and lateral views; (c) 3-D CAD image; (d,e) Titanium *MeSH*, adaptation and mock surgery on CAM medical model; (f) Right fronto-zygomatic region fixed with a single 2-hole plate (+gap).

and functional, typically via invasive, intricate, costly and lengthy orthognathic surgeries.

Likewise, in the cranio-maxillo-facial complex, orthognathic surgery offers significant improvement in the emotional, psychological, functional, esthetic and socioeconomic QoL of patients. The first total LeFort I osteotomy was performed by Wassmund in 1927 for correcting skeletal open bite.⁵ Since then, technical and technological advancements in orthognathic surgery concepts; elaborate in the diagnosis and treatment planning for the correction of jaw and dento-facial deformities, have been impressively considerable in achieving stable orodental functional occlusion and facial esthetic harmony. Undeniably, this can be attributed to the integration of modern and innovative facial analysis and computer-aided imaging exams into well-orchestrated and executed orthodontic and surgical methods. Three-Dimensional (3-D) *virtual surgical planning* is a fine example.⁶

For the non-OMFS audience, a brief illustration depicting a couple of our cases is provided below, to reveal the challenging severity and appreciate the intricacy of such conditions.

Nowadays, the acquisition of 3-D images of a patient's craniofacial complex via cone-beam computed tomography (CB-CT), supported by software tools allowing the construction of 3-D dynamic and interactive visual models, eliminates the uncertainty experienced with two-dimensional images. Thereby allowing for a more accurate or predictable treatment plan and effectual surgery, especially for patients with complex dento-facial deformities.^{6,7} Currently, dentists extensively use such digital technologies to rapidly design, plan and execute longer-lasting veneers, crowns, inlays/onlays, dentures, orthodontic treatment and full-mouth reconstructions. Further, combining the use of 3-D imaging and CAD/CAM (computer-aided design

and manufacturing) technology aids in the diagnosis and treatment of complex facial contour deformities and provides the surgeon with confidence and several advantages over the use of stock implants. For example, in cases requiring the correction of uni-lateral deformities, mirror-imaging software is being used to fabricate an implant to duplicate the opposite facial skeleton. CAD/CAM-assisted customized implant fabrication, allows more precise fit and a shorter surgical time and expertise in bone restructuring, when compared to stock implants. Recent advances and acceptance of including 3-D printing in our every-day practises and training programs, facilitated the attainment of fresh directions and horizons, in numerous stages of surgery;^{6,7} including the precise assessment of patient anatomy, efficient treatment planning, and in simulating compound surgical procedures.

On the 11th of September of 2017, Materialise, a Belgian 3-D printing leading company, in collaboration with DePuy Synthes (part of the Johnson & Johnson Medical Devices Company), announced obtaining the US Food and Drug Administration (FDA) approval of 3-D printed and patient-specific/personalized titanium implants, under the TRUMATCH® CMF brand, for use in maxillofacial orthognathic surgery. It is the first 3D-printed titanium maxillofacial implant to receive US market clearance. The implants are designed and printed based on a cranial Computed Tomography (CT) scan of the specific patient skull. For more information, please try and consult: <http://www.materialise.com/en/press-releases/materialises-3d-printed-maxillofacial-implants-titanium-are-first-to-get-green-light> and/or <https://3dprintingindustry.com/news/materialise-3d-printed-implants-facial-reconstruction-available-usa-121096/>

It is noteworthy herein that the US-FDA cleared in 2015 the first 3-D printed load-bearing device for long-term

implantation: SpineFab VBR, from Oxford Performance Materials, Inc., USA. It is a polymeric vertebral body replacement intended for use in the thoraco-lumbar regions of the spine to replace collapsed, damaged, or unstable vertebral bodies due to trauma or tumor. Available in 48 sizes, thus, it is not customizable or personalized.

The Leuven-based system started development in 2010 and was introduced in 2016 and has been tested for corrective jaw surgery and complex facial reconstruction and augmentation in Europe (except France) and Australia, with positive outcomes and consequences, including aesthetics and surgical OR time, via combining virtual surgical planning, 3-D printed surgical guides and implants, thereby widening/offering new treatment possibilities to perform more complex surgeries or multiple procedures in a single intervention. Yet another huge step for 3-D printing in the US health care industry. Noteworthy here in is the 2017 implementation of an in-House specialized 3-D planning, printing and bio-fabrication unit at the Royal Brisbane and Women's Hospital, located in the Herston Health Precinct in Brisbane, Queensland, Australia; a World's first; and won't be last. The unit creates custom and surgically-implantable screws, plates and chips (bone grafts), and aims to soon extend to tissues/organs made from patient's own cells.

While rigid internal fixation, to align bone segments or fracture fragments, using metallic materials has been in use for the last 40 years or so, Sir William Lane, over a hundred years ago, was the first to describe an osteo-synthesis plate.⁸ Micro-fixation⁹ using customized Titanium components overcome common intrinsic shortcomings of other systems

or devices; such as inter-fragmentary instability, inter-osseous wiring and the number of points of fixation for the placement of wires, corrosion or susceptibility thereof.

Advances in computer-aided 3-D design, planning and manufacturing technologies revealed, with great hype and hope, the benefits of an increasing utility and wide applications for precise virtual surgical planning in orthognathic surgery, especially when compared to conventional 2-D methods and tools. Costs, time and learning curves are amongst the main limitations and/or hurdles facing such technologies, to date.^{9,10} On the other hand, society is facing great challenges in surgical medicine and dentistry due to the increasing world population and the inherent desire of man-kind to maximize life expectancy, aesthetics and QoL. The demand for orthopaedic, cranial, maxillofacial and dental implants is closely linked to an ageing population and is also related to the increasing number of bone fractures that result from trauma: sports injuries and accidents.

This new miniaturized and customizable system and/or device probably provides attractive biomechanical strength and overcomes current obstacles; and perhaps combats the forces of masticatory muscles for proper facial height and dental occlusion; well, pending our personal, certainly amongst others, clinical testing: *Ojalá, muy pronto!*

Ultimately, one can foresee all hospitals and clinics housing 3-D printing facilities to supply personalized/custom-fabricated components and devices, for those undergoing surgeries after serious traumatic accidental or sport injuries, as well as cancer patients.

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